UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

SANDRA KOTHARI and SHANOOP KOTHARI, INDIVIDUALLY, and as HEIRS TO THE ESTATE OF H. K., DECEASED MINOR,	§	
Plaintiffs,	§	CIVIL ACTION NO._____
VS.	§	
TRIAD GROUP, INC.	§	
Defendant.	§	**JURY TRIAL DEMANDED**

PLAINTIFFS' ORIGINAL COMPLAINT

COME NOW, Plaintiffs, SANDRA KOTHARI and SHANOOP KOTHARI, individually and as heirs to the estate of H.K., deceased minor, and file this their Original Complaint against Defendant, TRIAD GROUP, INC., and for causes of action would respectfully show unto the court as follows:

I. Parties

1. Plaintiffs SANDRA KOTHARI and SHANOOP KOTHARI are individual citizens of the State of Texas.

2. Defendant TRIAD GROUP, INC. ("Triad") is a Wisconsin corporation with a principal place of business in Wisconsin. Triad can be served through its registered agent for service of process, **Donna L. Petroff, 700 West North Shore Drive, Hartland, Wisconsin 53029**.

II. Jurisdiction and Venue

3. Subject matter jurisdiction is conferred on this Court pursuant to 28 USC § 1332(a), as the amount in controversy exceeds seventy-five thousand dollars ($75,000.00) (excluding interest and costs).

4. Plaintiffs are citizens of the United States of America and the State of Texas and are

residents of Houston, Harris County, Texas. Triad is a corporation duly organized under the laws of the State of Wisconsin with it principle places of business located in said state. Therefore, pursuant to 28 USC § 1332(c)(1), Triad is a citizen of Wisconsin. This Court has original jurisdiction under 28 USC § 1332(a)(1) as there is complete diversity of citizenship.

5. Venue is proper in the Southern District of Texas, Houston Division, under 28 USC §1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in Harris County, Texas.

III. Facts

6. Sandra and Shanoop Kothari are the natural parents of H.K. who was born on October 23, 2008.

7. H.K. died on December 1, 2010.

8. In August, 2010, two year old H.K. was playing at home when he fell off the sofa. He bumped his head and cried, but did not lose consciousness. His parents took him to their family doctor who ordered a CT scan. The CT scan was negative for any injury from the fall, but it revealed that H.K. had an arachnoid cyst – a benign cyst between the brain or spinal cord and the arachnoid membrane that is usually present at birth.

9. Mr. and Ms. Kothari were referred to Dr. Stephen Fletcher, Chief of the Division of Pediatric Neurosurgery at The University of Texas Neurosurgeons for Children for the treatment of H.K.'s condition.

10. In September, 2010, H.K. underwent a MRI and EEG, the results of which helped to confirm the presence and size of the arachnoid cyst. While H.K. had excellent coordination and displayed no sign of developmental delays, the arachnoid cyst posed a risk for future problems. Dr. Fletcher spent a great deal of time with Mr. and Ms. Kothari discussing the issues, explaining the

risks, and it was determined that the best course of action was to surgically address the cyst.

11. On September 20, 2010, Dr. Fletcher performed a left frontotemporal craniotomy and fenestration (opening for drainage) of the arachnoid cyst at Children's Memorial Hermann Hospital in Houston, Texas. There were no complications and H.K. tolerated the procedure well and he was discharged home.

12. H.K. had a usual course of recovery from the surgery that included follow up visits with Dr. Fletcher. H.K. was running, playing and had picked up more words in his young vocabulary.

13. On October 28, 2010, Dr. Fletcher noted that there was some bulging of the bone flap on H.K.'s head caused by cerebrospinal fluid ("CSF") leaking from the surgical incision in the dura, which is a known risk. Dr. Fletcher put H.K. on Diamox to decrease the CSF production.

14. The CSF leak persisted, so on November 8, 2010 H.K. was admitted to Children's Memorial Hermann Hospital for the placement of a lumbar drain, which is a small in-dwelling catheter inserted through the low back into the subarachnoid space, providing access to the CSF.

15. The CSF from the lumbar drain was cultured to rule out an infection as the cause of the CSF leak. The cultures were all negative. The cause of the leak was suspected to be due to an allergic reaction to the dural repair system used during the craniotomy.

16. The lumbar drain was replaced on November 22, 2010. Multiple specimens were cultured at that time, the results of which showed no sign of infection. H.K. continued to do well, with normal activities, no neurologic symptoms and no fever.

17. Over the next several days, CSF was drawn from the lumbar drain daily for culture. This process involved sterilizing the area around the lumbar drain using alcohol wipes, pads and/or swabs. The alcohol wipes, pads and/or swabs used during H.K.'s treatment for the cleaning and

sterilizing of the lumbar drain were manufactured by Triad.

18. H.K. made steady improvement such that he was scheduled to be discharged on November 29, 2010. Just hours before he was going to go home, on the night of November 28, 2010, H.K. began to experience agitation and episodes of vomiting. He began to have an elevated temperature. He developed seizures and became tachycardic. Dr. Fletcher drew CSF from the lumbar drain and sent it for culture.

19. While undergoing a CT scan on the early morning of November 29, 2010, H.K. stopped breathing. He was emergently intubated, transferred to the PICU and placed on a ventilator. Intravenous antibiotics were started and a blood culture was obtained.

20. The results of the November 28 and 29, 2010 cultures of CSF and blood came back on November 30, 2010 and were positive for *Bacillus* cereus, a potentially life threatening bacteria that is normally associated with food borne illnesses. *Bacillus* cereus is rarely found in hospital-acquired infections. *Bacillus* cereus is rarely associated with bacterial meningitis.

21. By November 30, 2010, the cerebral blood flow study was negative for blood flow and the neurological examination performed by PICU was consistent with brain death. The family consulted with a team of physicians and were advised that all future care was futile. They asked for a few final hours to be alone with their son.

22. H.K. was declared dead at 12:54 p.m. on December 1, 2010 at the age of 2.

23. The cause of H.K.'s death was determined to be acute bacterial meningitis with septicemic syndrome of *Bacillus* cereus, leading to multi-organ failure.

24. Triad manufactured alcohol prep pads, swabs and swabsticks and introduced those alcohol prep products into the stream of commerce.

25. The Triad alcohol prep pads, swabs and swabsticks used in H.K.'s care were in the

same condition at the time they were used as when they left Triad's manufacturing facility.

26. Some or all of Triad's alcohol prep pads, swabs and swabsticks were contaminated with *Bacillus* cereus.

27. On January 3, 2011, Triad issued a letter to all of its customers regarding an "Urgent Drug Recall" for "ALL LOTS" of its "ALCOHOL PREP PADS, ALCOHOL SWABS, and ALCOHOL SWABSTICKS" due to the contamination of the products "with an objectionable organism." This recall involved all products marked as STERILE as well as non-sterile products.

28. On January 5, 2011, the FDA announced a recall of "ALL LOTS of ALCOHOL PREP PADS, ALCOHOL SWABS, and ALCOHOL SWABSTICKS manufactured by Triad Group" including those manufactured for private labeling by: Cardinal Health, PSS Select, VersaPro, Boca/Ultilet, Moore Medical, Walgreens, CVS, and Conzellin. The recall was initiated because Triad's alcohol prep products were potentially contaminated with *Bacillus* cereus. Triad's recall stated that use of Triad's contaminated products "could lead to life-threatening infections, especially in at risk populations, including immune suppressed and surgical patients." These products were distributed in the United States, Canada and Europe.

29. Triad alcohol prep products are included in pre-packaged pharmaceutical products used throughout the healthcare industry. Because of this, the FDA and many pharmaceutical companies have issued recalls for certain prepackaged pharmaceuticals containing Triad alcohol prep products. The only reason for these recalls is the potentially contaminated Triad alcohol prep product included in the package. The pre-packaged products include:

- Bayer HealthCare Pharmaceuticals for its Betaseron product;
- GlaxoSmithKline for its ARIXTRA Starter Kits;
- Genentech, Inc., a member of the Roche, for Boniva Injection, Fuzeon, Nutropin A.Q. Pen, Pegasys, and TNKase products;
- Progenics Pharmaceuticals Inc. and Pfizer Inc. for its Relistor injection kits;
- Merck & Co., Inc. for its Pegintron product;

- Teva Pharmaceutical Industries for its Copaxone product.
- Novaris Pharmaceuticals for its Extavia (interferon beta 1-b) product;
- Watson Pharmaceuticals for its Trelstar product; and,
- Neuro Resource Group, Inc. for its medical devices and products for injury management, rehabilitation, and pain management.

30. Following the Triad recall, Children's Memorial Hermann Children's Hospital pulled all Triad products from hospital inventory.

IV. Cause of Action - Strict Products Liability

31. Plaintiffs incorporate herein by reference for this strict products liability cause of action paragraphs 6 - 30.

32. Triad, as the manufacturer and distributor of the alcohol wipes, pads and swabs at issue, owed Plaintiffs a duty to ensure that the alcohol pads and swabs were safe and otherwise fit for their intended use.

33. Triad breached its legal duty to Plaintiffs by manufacturing and distributing alcohol wipes, pads and swabs that were defective and unreasonably dangerous, rendering them unsafe for their normal, intended use.

34. The alcohol wipes, pads and swabs manufactured by Triad and used on H.K. were defective and unreasonably dangerous due to *Bacillus* Cereus contamination.

35. The alcohol wipes, pads and swabs were defective at the time they were manufactured, distributed and placed into the stream of commerce by Triad.

36. The alcohol wipes, pads and swabs were delivered to Children's Memorial Hermann Hospital and reached Plaintiffs in a defective condition, and they were thereafter used to clean and sterilize H.K.'s lumbar drain.

37. The manufacturing defect in the alcohol wipes, pads and swabs was a producing cause of the injury and death of H.K. and the damages suffered by Plaintiffs.

38. Triad is strictly liable to Plaintiffs by providing defective and unreasonably dangerous products.

V. Cause of Action - Negligence and Gross Negligence

39. Plaintiffs incorporate herein by reference for this negligence and gross negligence cause of action paragraphs 6 - 30.

40. Triad owed a legal duty to Plaintiffs to ensure that its alcohol wipes, pads and swabs and its facilities were not contaminated with *Bacillus* Cereus or other bacteria harmful to humans.

41. Triad had a duty to exercise reasonable care to ensure that its manufacturing process for alcohol wipes, pads and swabs was not contaminated and free of defects.

42. Triad owed a duty to inspect its facilities and manufacturing process for contamination and defects and to test its products for contamination and defects.

43. Triad breached the duties it owed to Plaintiffs.

44. Triad knew or should have known through the exercise of reasonable care that the alcohol wipes, pads and swabs were not properly manufactured, tested or inspected for contamination and defects.

45. Triad knew or should have known through the exercise of reasonable care that its failure to properly manufacture, test or inspect its alcohol wipes, pads and swabs for contamination and defects would cause harm to people who use those products.

46. Triad's conduct constitutes negligence and such negligence was a proximate cause of the injuries to and death of H.K. and the damages suffered by Plaintiffs.

47. Triad's conduct, which when viewed objectively from its standpoint at the time of its occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Triad had actual, subjective awareness of the risk involved, but

nevertheless proceeded with conscious indifference to the rights, safety or welfare of others. Consequently, Triad's conduct constitutes gross negligence. Such gross negligence was a proximate cause of the occurrence in question, the death of H.K. and Plaintiff's injuries and damages.

VI. Wrongful Death Act and Survival Statute

48. Triad's conduct was a producing and/or proximate cause of the injuries to and death of H.K.. Prior to his death, H.K. was a healthy and able bodied person.

49. H.K. was two years old at the time of his death and he died intestate. His parents are the sole legal heirs of his estate. At this time there is no probate pending and none is necessary under the laws of the State of Texas.

50. Sandra and Shanoop Kothari are H.K.'s natural parents. They are statutory wrongful death claimants and they seek recovery for the actual damages each has suffered as a result of the wrongful death of H.K. pursuant to TEX. CIV. PRAC. & REM. CODE § 71.001, *et seq.*, the "Texas Wrongful Death Act." Each also seeks recovery of exemplary damages for the wrongful death of H.K..

51. The incident and resulting injuries did not immediately take H.K.'s life. Rather, he endured extreme conscious physical pain, suffering and mental anguish during and after the incident in question, but before his death. Pursuant to TEX. CIV. PRAC. & REM. CODE §71.021, commonly referred to as the "Survival Statute," Plaintiffs seek recovery from Triad for the injuries and damages that H.K. suffered prior to his death

VII. Damages

52. As a result of the incident made the basis of this lawsuit described in the preceding paragraphs and the wrongful conduct of Triad, Plaintiffs sustained significant injuries and damages in the past and will in reasonable probability sustain these damages in the future.

53. Plaintiffs Sandra and Shanoop Kothari as sole legal heirs to the estate of H.K., deceased, respectfully requests that the jury determine the amount of pain and mental anguish damages H.K. sustained prior to his death and they seek recovery for the same.

54. Plaintiffs Sandra and Shanoop Kothari, as natural parents of H.K., seek recovery for the medical expenses incurred in the treatment of H.K. before his death and the funeral and burial expenses incurred. They also seek recovery for the monetary value of the damages and losses they each have incurred in the past and, in reasonable probability, will sustain in the future, resulting from the wrongful death of their son, including:

a. Pecuniary loss;

b. Loss of companionship and society; and

c. Mental anguish.

55. Plaintiffs seek recovery for exemplary damages because of Triad's grossly negligent conduct.

VIII. Jury Demand

56. Pursuant to FRCP 38, Plaintiffs respectfully demand a jury trial for all issues so triable.

Prayer for Relief

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that Triad Group, Inc. be cited to appear and answer herein and that upon final hearing Plaintiffs have judgment against Triad Group, Inc. for:

1. Judgment against Triad for the harms and damages its defective products caused to Plaintiffs;

2. Pre-judgment interest from the date of judgment at the legal rate;

3. Post-judgment interest at the legal rate;

4. Exemplary damages;

5. All court costs associated with this suit; and,

6. For such other and further relief at law or in equity as the court may deem proper.

Respectfully submitted,

PERDUE & KIDD, L.L.P.

By: _____

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